UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,301	02/01/2002	Yusuke Nakamura	1254-0195P	7091

2292 7590 08/09/2005

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
KIM, YOUNG J	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/060,301	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

5.02

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on June 13, 2005 has been entered.

Preliminary Remark

The addition of claims 6-8 are acknowledged.

Claims 1-3 and 5-8 are pending and are under prosecution therefore.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method involving the amplification which employs 40 ng of DNA per 100 sites, does not reasonably provide enablement for a method of amplification which employs lesser than 40 ng of DNA per 100 sites. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation are summarized in In Re Wands (858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988)). They include (A) the quantity of experimentation necessary, (B) the amount of direction or guidance presented, (C) the presence or absence of working examples, (D) the nature of the invention, (E) the state of the prior art, (F) the relative skill of those in the art, (G) the predictability or unpredictability of the art, and (H) the breadth of the claims.

Nature of the Invention

The nature of the invention relates to multiplex amplification of a plurality of target sites, involving a limited amount of starting DNA, in the instant case, 10-40 ng of DNA per 100 target sites, followed by the detection of target sites, in the instant case, polymorphisms, via Invader® assay or Taqman® PCR. Whether the specification as filed is enabling for a method involving multiplex amplification of 100 target sites employing the amount of less than 40 ng DNA is the subject of the discussion.

Breadth of the Claims

The breadth of the claims 1-3 range from simultaneously amplifying 2 sites employing 0.2-0.4 ng of starting DNA to simultaneously amplifying 100 sites employing 10-40 ng of DNA.

The breadth of the claims 5-8 range from simultaneously amplifying a single site employing 0.1-0.2 ng of starting DNA to simultaneously amplifying 100 sites employing 10-40 ng of DNA.

Unpredictability of the art

Whether a trace amount of starting DNA, in this case, as little as 10 ng, can be used to successfully conduct a multiplex reaction simultaneously amplifying 100 sites. For example,

Mein et al. (Genome Research, March 2000, vol. 10, no. 3, pages 330-343), discloses a method of multiplex amplification of plurality of target polymorphic sites, 36 sites (abstract; page 341, 2nd column, 2nd paragraph), employing 30 multiplex primer sets (Table 4), followed by the Invader assay® of the amplicons for the detection of polymorphisms (page 341, 2nd column, bottom paragraph to page 351, 1st column, 1st paragraph).

The amount of genomic DNA employed for the amplification reaction is disclosed as being 10 ng (page 341, 2nd column, 2nd paragraph, middle), which translates to 0.3 ng of DNA per site.

Hence, while the artisans amplified far less target sites employing more starting DNA amount, than the instantly claimed 100 sites, artisans note that the detection was achieved with 99.2%, wherein the artisans attribute the 2.3% failure rate, **explicitly** to PCR failure (Abstract; page 340, 1st column, 2nd paragraph).

Wang et al. (Science, May 1998, vol. 280, pages 1077-1082[1]), conducts a multiplex amplification of 558 loci (page 1080, 3rd column 2nd paragraph) employing 100 ng of DNA (page 1082, 2nd column 1st paragraph), which necessarily translates to 0.17 ng of DNA per target site. The artisans demonstrate that the 50% of the multiplex amplification failed (page 1080, 3rd column, 1st paragraph), evidencing the unpredictable nature of successfully amplifying a target DNA of minute amount of DNA in a multiplex amplification reaction.

Absence of Working Example

The instant specification is clearly absent in giving a single example of achieving multiplex amplification of 100 sites employing the lower limits of starting DNA amount. In fact,

[1] IDS received on February 2, 2005.

the instant specification gives a single example of employing 40 ng of starting DNA in multiplex amplification reaction amplifying 100 target sites (page 15, *Example 2*).

Amount of Guidance

On page 19, the specification discloses that the PCR product obtained from Example 2 was diluted and 8 µl of the diluted PCR product was dispensed into each well of a card (see 4th paragraph). It should be noted that the PCR product generated from Example 2, as noted above, was amplified employing 40 ng of the starting DNA amplifying 100 target sites (page 15).

The each well containing the diluted PCR product is then tested via Invader assay (page 19, bottom paragraph to 1st paragraph, page 20), wherein correlation is made that only 0.1 ng of *genomic* DNA was used as template. This appears to be contrary to what Example 2 teaches, as Example 2 is abundantly clear that 40 ng of DNA was used for amplifying 100 target regions:

> Example 2: Amplification of genomic DNA
>
> PCR was performed with a 50 µl system using 40 ng of the genomic DNA obtained in Example 1. A reaction solution contains 200 types of primer (50 pmol each, 100 pairs, SEQ ID NOS: 1 to 200), 10 units of EX-TaqDNA polymerase (Takara Shuzo), and 0.55 µg of TaqStart (CLONTECH Laboratories). TaqStart is an antibody for EX-TaqDNA polymerase. The hot start method can be performed by adding TaqStart to the reaction solution.
>
> PCR was performed with GeneAmp PCR system 9700 (Applied Biosystems). After DNA was denatured at 94℃ for 2 min, a cycle consisting of a denaturation process at 94℃ for 15 sec, an annealing process at 60℃ at 45 sec, and then an extension process at 72℃ for 3min was repeated 35 times, followed by extension at 72℃ for 3min.

Additionally, if the specification intended to mean that only 0.1 ng of the amplicons were needed to achieved detection via Invader® assay, thereby correlating that only 10 ng of

amplicons were needed for detecting 100 target sites, then such disclosure would not provide proper guidance for simultaneously amplifying 100 target sites employing only 10 ng of starting DNA.

Quantity of Experimentation

As discussed above, a skilled artisan, absent guidance from the instant specification or that of the prior art which guides said skilled artisan for conducting multiplex amplification using trace amount of starting DNA, in this case, less than 40 ng of DNA for simultaneously (or multiplexing) amplifying 100 target sites, would require undue experimentation.

Skill level

The artisan with respect to the undue experimentation criteria is established is considered high.

State of art

As already discussed above, art of record, Mein et al. (Genome Research, March 2000, vol. 10, no. 3, pages 330-343) and Wang et al. (Science, May 1998, vol. 280, pages 1077-1082), demonstrates the unpredictability in multiplex amplification of a plurality of target sites employing trace amounts of DNA.

Given the highly unpredictable nature of multiplex amplification, one of skill in the art, absent specific guidance from the teachings in the specification or in the prior art, would not be able to amplify the lower range of the starting DNA as claimed in the instant claims, requiring undue experimentation of a skilled artisan to practice the invention commensurate in scope of the instant claims.

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

The instant specification as originally filed does not have written description basis for a method achieving at least 98% success in detecting single nucleotide polymorphisms for a method employing starting DNA amount other than 40 ng.

The section in which the limitation, "with the result that at least 98% of single nucleotide polymorphisms are detected," can be found is on pages 15-19 of the instant specification where 40 ng of starting DNA (page 15, second paragraph) is employed for simultaneously amplifying 100 target sites (page 15, 3rd paragraph), followed by the Invader assay typing for single nucleotide polymorphisms in the resulting amplicons (page 18, 1st paragraph), which resulted the detection of fluorescence in 98% of SNPs (page 19, 1st paragraph).

Thus, the instant specification as originally filed only contemplates 98% detection for a method involving 40 ng of DNA and not for any amount lower.

Claim Rejections - 35 USC § 102

The rejection of claims 1 and 5 under 35 U.S.C. 102(b) as being anticipated by Wang et al. (Science, May 1998, vol. 280, pages 1077-1082), maintained in the Office Action mailed on July 14, 2004 is withdrawn in view of the Amendment received on June 13, 2005.

The rejection of claims 1, 2, and 4 under 35 U.S.C. 102(b) as being anticipated by Walburger et al. (Mutation Research, January 2001, vol. 432, pages 69-78), maintained in the Office Action mailed on July 14, 2004 is withdrawn in view of the Amendment received on June 13, 2005.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Mein et al. (Genome Research, March 2000, vol. 10, no. 3, pages 330-343).

Mein et al. disclose a method of coupling multiplex amplification of polymorphic loci from a genomic DNA, followed by detecting the single nucleotide polymorphisms by Invader® assay method (Abstract, page 331, 2nd column; page 341, 2nd column, 2nd and 3rd paragraphs).

Mein et al. disclose that 36 SNPs sites were amplified (page 331, 2nd column), employing 10 ng of starting DNA, which translates to 0.27 ng of DNA per target site.

Instant claims 1 and 5 require a simultaneous amplification employing 10-40 ng of DNA per 100 sites, which translates to 0.1 to 0.4 ng of DNA per target site.

The detection confidence is disclosed as being 99.2% (page 340, 1st column, 2nd paragraph).

Mein et al. clearly anticipates the invention.

Claim Rejections - 35 USC § 103

The rejection of claims 2 and 3 under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (Science, May 1998, vol. 280, pages 1077-1082) in view of Brooks (US 2001/0046670 A1, issued November 29, 2001, priority October 7, 1999), maintained in the Office Action mailed on July 14, 2004 is withdrawn in view of the Amendment received on June 13, 2005.

The rejection of claim 3 under U.S.C. 103(a) as being unpatentable over Walburger et al. (Mutation Research, January 2001, vol. 432, pages 69-78) in view of Wang et al. (Science, May 1998, vol. 280, pages 1077-1082), maintained in the Office Action mailed on July 14, 2004 is withdrawn in view of the Amendment received on June 13, 2005.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mein et al. (Genome Research, March 2000, vol. 10, no. 3, pages 330-343) in view of Wang et al. (Science, May 1998, vol. 280, pages 1077-1082).

Mein et al. disclose a method of coupling multiplex amplification of polymorphic loci from a genomic DNA, followed by detecting the single nucleotide polymorphisms by Invader® assay method (Abstract, page 331, 2nd column).

Mein et al. disclose that 36 SNPs sites were amplified (page 331, 2nd column), employing 10 ng of starting DNA, which translates to 0.27 ng of DNA per target site.

Mein et al. do not employ 50 or more primer pairs in their method.

Wang et al. disclose a method of detecting SNPs by first simultaneoutly amplifying (or multiplexing) a plurality of primer pairs, including 558 loci, necessarily including more than 50 primer sets, considering that a singe primer set amplifies a single loci (page 1080, 3rd column).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Mein et al. with the teachings Wang et al. to arrived at the claimed invention for the following reasons.

The motivation to multiplex more target sites in amplification, that is, simultaneously amplifying multiple target sites, is a well-established desire in the art. As Wang et al. put it:

> "We next sought to **decrease substantially the sample preparation required to generate large numbers of SNPs, as required to perform a genome scan. We developed a protocol based on multiplex PCR in which primer pairs from many different loci are combined in a single reaction**." (page 1080, 3rd paragraph, 1st paragraph)

Wang et al. employ 100 ng of DNA for simultaneously amplifying a plurality of loci, including 24 sets of approximately 23 loci, 12 sets of approximately 46 loci, 6 sets of approximately 92 loci (page 1080, 3rd paragraph, 1st paragraph), and a single set of 558 loci.

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings of Mein et al. with the teachings of Wang et al. to arrive at simultaneously amplification involving at least 50 pairs of primers or more.

It is noted that when Wang et al. conducted multiplex amplification involving a single set of 558 loci, the artisans achieved 50% detection test.

However, Wang et al. also discusses that it may be possible to salvage the unsuccessful assays by grouping them into additional multiplex sets or by *redesigning* the assays.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings of Mein et al. and the teachings of Wang et al. to achieve multiplex amplification involving a plurality of primers for the advantage of decreasing sample preparation (as expressed by Wang et al.), wherein the artisan would have had a reasonable expectation of success at such combination as Wang et al. clearly envisions that by redesigning, multiplexing even up to 558 loci would be achievable, through optimization.

Regarding optimization, the MPEP 2144.05(II)(A) clear that, "differences in concentrations or temperature ***will not support*** patentability of subject matter encompassed by prior art unless there is evidence indicating such concentration or temperature is critical," citing *In re Aller,* F.2d 454, 456, 105 USPQ 233, 235, (CCPA 1995). Analogously, optimizing parameters for multiplexing multiple target sites in an amplification reaction would be considered routine, as provided for by Wang et al.

Therefore the invention as claimed is *prima facie* obvious over the cited references.

Claims 2 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mein et al. (Genome Research, March 2000, vol. 10, no. 3, pages 330-343) in view of Brooks (US 2001/0046670 A1, issued November 29, 2001, priority October 7, 1999).

The teachings of Mein et al. have already been discussed above.

Mein et al. do not employ "hot start" amplification (claims 2 and 6)

Brook discloses a multiplex amplification [0076] reaction which involves hot start amplification [0066].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Mein et al. with the advantage offered by Brooks to arrive at the invention as claimed for the following reasons.

Brook clearly discusses the advantage of employing "hot start" PCR method:

"...other 'Hot Start' type PCR conditions are used to limit primer dimmer artifacts as much as possible." [0066].

As one of ordinary skill in the art in the art of amplification would recognize that primer dimmer artifacts are to be minimized in amplification procedures, it would have been obvious to implement this teachings into the teachings of Mein et al. to arrive at the claimed invention with a reasonable expectation of success.

Therefore, the invention as claimed is *prima facie* obvious over the cited references.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mein et al. (Genome Research, March 2000, vol. 10, no. 3, pages 330-343) in view of Wang et al. (Science, May 1998, vol. 280, pages 1077-1082) and Brooks (US 2001/0046670 A1, issued November 29, 2001, priority October 7, 1999).

Mein et al. disclose a method of coupling multiplex amplification of polymorphic loci from a genomic DNA, followed by detecting the single nucleotide polymorphisms by Invader® assay method (Abstract, page 331, 2nd column).

Mein et al. disclose that 36 SNPs sites were amplified (page 331, 2nd column), employing 10 ng of starting DNA, which translates to 0.27 ng of DNA per target site.

Mein et al. do not employ "hot start" PCR method, wherein in said hot start PCR method, 50 or more primer pairs are employed.

Wang et al. disclose a method of detecting SNPs by first simultaneoutly amplifying (or multiplexing) a plurality of primer pairs, including 558 loci, necessarily including more than 50 primer sets, considering that a singe primer set amplifies a single loci (page 1080, 3rd column).

Brook discloses a multiplex amplification [0076] reaction which involves hot start amplification [0066].

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Mein et al. with the teachings Wang et al. and Brooks to arrived at the claimed invention for the following reasons.

The motivation to multiplex more target sites in amplification, that is, simultaneously amplifying multiple target sites, is a well-established desire in the art. As Wang et al. put it:

> "We next sought to **decrease substantially the sample preparation required to generate large numbers of SNPs, as required to perform a genome scan. We developed a protocol based on multiplex PCR in which primer pairs from many different loci are combined in a single reaction**." (page 1080, 3rd paragraph, 1st paragraph)

Wang et al. employ 100 ng of DNA for simultaneously amplifying a plurality of loci, including 24 sets of approximately 23 loci, 12 sets of approximately 46 loci, 6 sets of approximately 92 loci (page 1080, 3rd paragraph, 1st paragraph), and a single set of 558 loci.

Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings of Mein et al. with the teachings of Wang et al. to arrive at simultaneously amplification involving at least 50 pairs of primers or more.

It is noted that when Wang et al. conducted multiplex amplification involving a single set of 558 loci, the artisans achieved 50% detection test.

However, Wang et al. also discusses that it may be possible to salvage the unsuccessful assays by grouping them into additional multiplex sets or by *redesigning* the assays.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the teachings of Mein et al. and the teachings of Wang et al. to achieve multiplex amplification involving a plurality of primers for the advantage of decreasing sample preparation (as expressed by Wang et al.), wherein the artisan would have had a reasonable expectation of success at such combination as Wang et al. clearly envisions that by redesigning, multiplexing even up to 558 loci would be achievable, through optimization.

Regarding optimization, the MPEP 2144.05(II)(A) clear that, "differences in concentrations or temperature ***will not support*** patentability of subject matter encompassed by prior art unless there is evidence indicating such concentration or temperature is critical," citing *In re Aller,* F.2d 454, 456, 105 USPQ 233, 235, (CCPA 1995). Analogously, optimizing parameters for multiplexing multiple target sites in an amplification reaction would be considered routine, as provided for by Wang et al.

With regard to employing hot start PCR method, Brook clearly discusses the advantage of employing hot start PCR method:

"...other 'Hot Start' type PCR conditions are used to limit primer dimmer artifacts as much as possible." [0066].

As one of ordinary skill in the art in the art of amplification would recognize that primer dimmer artifacts are to be minimized in amplification procedures, it would have been obvious to implement this teachings into the teachings of Mein et al. and Wang et al. to arrive at the claimed invention with a reasonable expectation of success.

Therefore the invention as claimed is *prima facie* obvious over the cited references.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m. The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE

SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Young J. Kim
Patent Examiner
Art Unit 1637
8/5/2005

YOUNG J. KIM
PATENT EXAMINER

yjk